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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/784,674 | 02/15/2001 | Karen W. Shannon | 10971464-3 | 3167 |

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AGILENT TECHNOLOGIES
Legal Department, 51UPD
Intellectual Property Administration
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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|---------------------------------|--------------------------------|
| Application No. 09/784,674 | Applicant(s) SHANNON ET AL. |
| Examiner Channing S. Mahatan | Art Unit 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-101 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

- 4) Interview Summary (PTO-413) Paper No(s) ____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: Attachment for PTO-948.

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DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

OBJECTION BY DRAFTSMAN

Applicants are hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicants required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

SEQUENCE COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a) (1) and (a) (2). This application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 due to the sequence as in the specification on page 46, line 4, etc., and no submission of the following items. Therefore, applicant is required to submit the following:

1. As a separate part of the disclosure on paper copy or compact disk copy, a "Sequence Listing" as 37 C.F.R. § 1.821(c).
2. A copy of the "Sequence Listing" in computer readable form as required by 37 C.F.R. § 1.821 (e).

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3. A statement that the content of the paper and computer readable copies are the same and include no new matter, as required by 37 C.F.R. § 1.821 (f) and 37 C.F.R. § 1.821 (g).
4. Each sequence in the specification is required to have a SEQ ID NO. therewith.

Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance requirement. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this office action.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-40 and 98-101, drawn to methods for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence utilizing a predetermined number of unique oligonucleotides within a nucleotide sequence, classified in class 702, subclass 20; and class 435, subclass 6. If this Group is elected, then the below summarized species elections are also required.
- II. Claims 41-97, drawn to methods for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence utilizing a set of overlapping oligonucleotides from a nucleotide sequence, classified in class 702, subclass 20; and class 435, subclass 6. If this Group is elected, then the below summarized species elections are also required.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-II each are directed to distinct methods of predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence. In Invention I a predetermined number of unique oligonucleotides within a nucleotide sequence are identified. In Invention II a set of overlapping oligonucleotides from a nucleotide sequence are identified/obtained. Invention I does not indicate that the oligonucleotides utilized are overlapping, further Invention II does not indicate that the oligonucleotides utilized are predetermined. It is acknowledged that the above methods for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence are classified within the same class and subclass, however such classification does not exclude such processes from restriction since it is shown that each invention contains divergent subject matter, and are distinctly different processes (directed to differing procedures as well as results). Each of these differing procedures requires a distinct search thus documenting the undue search burden if searched together.

FIRST SPECIES ELECTION GROUP APPLICABLE ONLY IF GROUP I OR II IS ELECTED

This application contains claims directed to the following patentably distinct species of the claimed invention:

- IA. Composition factors; claims 5, 6, 47, and 48.
- IB. Thermodynamic factors; claims 5, 7, 47, 49, 78, 79, and 82.
- IC. Chemosynthetic efficiencies; claims 5, 8, 47, and 52.
- ID. Kinetic factors; claims 5, 9, 47, and 53.

Currently, claims 1-5, 10-47, 50, 51, 54-77, 80, 81, and 83-101 are generic to all of the above species IA-ID. The following are definitions to the above distinct species, which justifies

and forms the basis of the species election requirement: IA. Composition factors are numerical factors based solely on the composition of sequence of an oligonucleotide without involving additional parameters (page 20, lines 27-29 of the Specification). IB. Thermodynamic factors are numerical factors that predict the behavior of an oligonucleotide in some process that has reached equilibrium (page 21, lines 10-13 of the Specification). IC. Chemosynthetic efficiencies are the observed efficiency of hybridization between an oligonucleotide and its complementary target (page 22, lines 1-8 of the Specification). ID. Kinetic factors are numerical factors that predict the rate at which an oligonucleotide hybridizes to its complementary sequence or the rate at which the hybridized sequence dissociates from its complement (page 22, lines 12-14 of the Specification). Thus, the search for the above species IA-ID is reasonably non-overlapping thus documenting this species election requirement due to the undue search burden that would exist if the search for prior art covered these non-overlapping species together.

SECOND SPECIES ELECTION GROUP APPLICABLE ONLY IF GROUP I OR II IS ELECTED

This application contains claims directed to the following patentably distinct species of the claimed invention:

IIA. Non-chemically modified nucleotides; claims 17, 18, 20, 21, 60, 61, 63, 64, 87, 88, 90, and 91.

IIB. Chemically modified nucleotides; claims 19, 22, 62, 65, 89, and 92.

Currently, claims 1-16, 23-59, 66-86, and 93-101 are generic to all of the above species IIA and IIB. Chemically modified nucleotides are nucleic acid polymers containing a modified base, sugar or phosphate group (page 17, lines 12-16 of the Specification). Chemical modification of nucleotides alters nucleotide function/composition to the extent that the above

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species are considered distinct. Thus, the search burden for the above species are non-overlapping thus supporting this specie election requirement due to an undue search burden if the species were examined together via two separate searches.

Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species for "each" of the above specie sets for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

INVENTORSHIP AMENDMENT

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *June 5, 2002*

Examiner Initials: *CSD*

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER